

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 7, 2018

Melissa Louis-Juste Regulatory Affairs Specialist PDI 100 Phillips Parkway Montvale, NJ 07645

Subject: Label and CSF Notification per PRN 98-10 – Revised to Update Basic and

Alternate CSF, Label revisions Product Name: Project Flash Spray EPA Registration Number: 9480-14 Application Date: 02/22/2018 Decision Number: 539314

Dear Ms. Louis-Juste:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 02/15/2018
- Alternate CSF 1 dated 02/15/2018

Page 2 of 2 EPA Reg. No. 9480-14 Decision No. 539314

Any CSFs other than those listed above are superseded/no longer valid.

The following alternate brand names have been added to the product record:

- Sani-Diff [TM] [®] Germicidal Spray
- Sani-Diff HP [TM] [®] Germicidal Spray
- Sani-HyPerCide [TM] [®] Germicidal Spray
- Sani-HyPeroxide [TM] [®] Germicidal Spray
- Sani-Diffex [TM] [®] Germicidal Spray
- Sani-DiffX [TM] [®] Germicidal Spray

If you have any questions, please contact Terria Northern at 703-347-0265 or by email at northern.terria@epa.gov.

Sincerely,

for

Zeno Bain, Product Manager 33 Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs

#### PROJECT FLASH SPRAY

#### NOTIFICATION

9480-14

Alternate brand names:
Sani-Diff [™] [®] Germicidal Spray
Sani-Diff HP[™] [®]Germicidal Spray
Sani-HyPerCide [™] [®]Germicidal Spray
Sani-HyPeroxide [™] [®] Germicidal Spray
Sani-Diffex [™] [®] Germicidal Spray

Sani-DiffX [™] [®]Germicidal Spray

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

05/07/2018

**ACTIVE INGREDIENTS:** 

Hydrogen Peroxide	4.04%
OTHER INGREDIENTS	95.96%
TOTAL	100 00%

# KEEP OUT OF REACH OF CHILDREN CAUTION

See back [side] panel for additional precautionary statements

NET CONTENTS \_\_\_\_\_fl. oz. [or qt. or mL or L]

EPA Reg. No.: 9480-14 EPA Est. No.: 9480-NY-1

Or

EPA Est. No. A=9480-NY-1, B=72956-AR-1 [or others] Alpha character will precede batch code on product

[Manufactured by [or for]]:
Professional Disposables International, Inc.
Two Nice-Pak Park, Orangeburg, NY 10962-1376 [USA]
[For information call: [phone number to be inserted]]
[Made in [USA] [with domestic and imported materials] [insert country]

[On any panel]

#### PRECAUTIONARY STATEMENTS:

#### Hazards to humans and domestic animals

**CAUTION:** Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet [or restroom].

#### FIRST AID:

Call a poison control center [or healthcare professional] [or doctor] for treatment advice. Have the product container or label with you when calling a poison control center [or healthcare professional] [or doctor] or going for treatment. [For additional information in case of emergency call the Poison Control Center toll free at 1-800-222-1222.]

**If in eye:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

#### Physical or chemical hazard:

This product contains an oxidizing agent. Avoid contact with other sanitizers, cleaners or organic substances.

#### **DIRECTIONS FOR USE:**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[[[This product] [Insert product name] is a "ready-to-use" liquid, comprised of 4.04% concentration of hydrogen peroxide.] [[It] should be used at full strength and should not be diluted before use.]]

TO DISINFECT [CLEAN] [AND DEODORIZE] HARD, NONPOROUS SURFACES: Spray [product name] 6-8 inches from surface until thoroughly wet. Allow surface to remain visibly wet for one (1) minute. For [Clostridium difficile] [C.difficile] spores allow surface to remain visibly wet for five (5) minutes. Let air dry [or wipe excess liquid using a towel]. A potable water rinse is required for food contact surfaces. If present, remove [gross filth] [and] [heavy] [soil loads] prior to disinfecting. A precleaning step is required to kill [Clostridium difficile] [or C.difficile] spores and Mycobacterium bovis BCG (TB).

OR

TO DISINFECT [AND DEODORIZE] HARD, NONPOROUS SURFACES: Spray [product name] 6-8 inches from surface until thoroughly wet. Allow surface to remain visibly wet for one (1) minute. For [Clostridium difficile] [C.difficile] spores allow surface to remain visibly wet for five (5) minutes. Let air dry [or wipe excess liquid using a towel]. If present, remove [gross filth] [and] [or] [heavy soil loads] prior to disinfecting. A precleaning step is required to kill [Clostridium difficile] [C.difficile] spores and Mycobacterium bovis BCG (TB). A thorough rinse with potable water is required for surfaces in direct contact with food. [If label includes cleaning claims for grease, soap scum, grime, dirt, messes, soil, add the following as the first sentence: A precleaning step is required for [grease], [soap scum], [grime], [dirt], [messes] [soil].]

OR

**TO [CLEAN] [AND] [,] [DISINFECT] [AND DEODORIZE] HARD, NONPOROUS SURFACES:** Remove [gross filth] [and] [or] [heavy soil]. Spray [product name] 6-8 inches from surface until thoroughly wet. Allow surface to remain visibly wet for one (1) minute. For [Clostridium difficile] [C.difficile] spores allow surface to remain visibly wet for five (5) minutes. Let air dry [or wipe excess liquid using a towel]. [A potable water rinse is required for food contact surfaces.] A precleaning step is required to kill [Clostridium difficile] [or C.difficile] spores and Mycobacterium bovis BCG (TB).

OR

TO [CLEAN] [AND] [,] [DISINFECT] [AND DEODORIZE] HARD, NONPOROUS SURFACES: Spray [product name] 6-8 inches from surface until thoroughly wet. Allow surface to remain visibly wet for one (1) minute. For [Clostridium difficile] [C.difficile] spores allow surface to remain visibly wet for five (5) minutes. Let air dry [or wipe excess liquid using a towel]. A potable water rinse is required for food contact surfaces. For heavily soiled surfaces, preclean prior to disinfecting. A precleaning step is required to kill [Clostridium difficile] [or C.difficile] spores and Mycobacterium bovis BCG (TB).

OR

**TO DISINFECT [AND DEODORIZE] HARD, NONPOROUS SURFACES**: To disinfect nonfood contact surfaces only: Remove heavy soil from surface. Spray [product name] 6-8 inches from surface until thoroughly wet. Allow surface to remain visibly wet for one (1) minute. For [Clostridium difficile] [C.difficile] spores allow surface to remain visibly wet for five (5) minutes. Let air dry [or wipe excess liquid using a towel]. A precleaning step is required to kill [Clostridium difficile] [or C.difficile] spores and Mycobacterium bovis BCG (TB).

OR

**TO DISINFECT [AND DEODORIZE] HARD, NONPOROUS SURFACES**: To disinfect nonfood contact surfaces only: Spray [product name] 6-8 inches from surface until thoroughly wet. Allow surface to remain visibly wet for one (1) minute. For [Clostridium difficile] [C.difficile] spores allow surface to remain visibly wet for five (5) minutes. Let air dry [or wipe excess liquid using a towel]. For [heavily] soiled surfaces, [pre] clean prior to disinfecting. A precleaning step is required to kill [Clostridium difficile] [or C.difficile] spores and Mycobacterium bovis BCG (TB).

PDI/9480-14/labels February 22, 2018 Page 2 of 10

[The following sets of directions are optional and for hospital/medical facility use only:]

[Norovirus Disinfection] [or Tuberculosis (TB) [Outbreaks]]: This product is effective against [Norovirus (as Feline calicivirus)] [or Mycobacterium bovis BCG (Tuberculosis)] in one minute at 68 °F (20°C). Norovirus Disinfection [and] [or] Tuberculosis (TB) Outbreaks on HARD, NONPOROUS SURFACES: [This product is effective against Norovirus (as Feline calicivirus) in one minute.] [This product is effective against Mycobacterium bovis BCG (Tuberculosis) in one minute at 69.8°F (21°C).] Spray [product name] 6-8 inches from surface until thoroughly wet. Allow surface to remain visibly wet for one (1) minute [or 60 seconds]. Let air dry [or wipe excess liquid using a towel]. [A potable water rinse is required for food contact surfaces.] If present, remove [gross filth] [and] [heavy] [soil loads] prior to disinfecting. Although efficacy at a 1 (one) minute contact time has been shown to be adequate against [Norovirus] [or TB], this time is not sufficient for [Clostridium difficile] [C.difficile] spores listed on the label. Therefore a 5 minute wet contact time must be used if [Clostridium difficile] [C.difficile] spores disinfection is required. A precleaning step is required to kill [Clostridium difficile] for C.difficile] spores and Mycobacterium bovis BCG (TB).

#### and/or

**Ultrasound transducers and probes:** For use on external surfaces of ultrasound transducers, scopes [and] [or] probes only prior to high-level disinfection [(HLD)].

To clean [and decontaminate] prior to high-level disinfection [HLD]: Preclean gel from external surface of ultrasound transducer or probe by using a clean washcloth. Then, follow instructions to disinfect.

†KILLS HIV-1 (AIDS VIRUS) AND HEPATITIS B VIRUS (HBV) IN 1 MINUTE ON THE PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS AND PRECLEANED EXTERNAL SURFACES OF ULTRASOUND TRANSDUCERS AND PROBES PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in 1 minute at room temperature (68°- 77°F) or (20°- 25°C) in healthcare or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) and Hepatitis B Virus (HBV).

# †SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 and HEPATITIS B VIRUS (HBV) ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

**Personal protection**: When handling HIV-1 (AIDS Virus) and HBV infected blood or body fluids; wear disposable protective gloves, protective gowns, masks and eye coverings, per facility protocol.

**Cleaning procedure**: All blood and other body fluids must be thoroughly cleaned from surfaces and objects before disinfection by the [germicidal] spray.

**Disposal of infectious materials**: Used towels that may be contaminated with blood and other body fluids should be disposed of according to local regulation for infectious waste disposal.

**Contact time**: Use [germicidal] spray to thoroughly wet surface. Allow surface to remain visibly wet for one (1) minute. Let air dry.

#### Special Instructions for cleaning prior to disinfection against *Clostridium difficile* spores.

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks and eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the sporicidal product. Cleaning is to include [vigorous] wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

**Infectious Waste Disposal:** Materials used in the cleaning process that may contain feces/waste are to be disposed of immediately in accordance with local regulations for disposal of infectious materials.

**To Disinfect:** Spray 6-8 inches from surface until surface is thoroughly wet. Allow surface to remain visibly wet for five (5) minutes, let air dry.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean and decontaminate critical or semi-critical medical devices prior to sterilization or [high level disinfection] [or HLD].

PDI/9480-14/labels February 22, 2018 Page 3 of 10

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**Storage:** Store this product in a cool, dry area, away from direct sunlight.

For a non-refillable container

**Spray Bottle** [or Container] [or Jug] Disposal: Nonrefillable container. Do not reuse or refill this container. Recycle empty container or discard in trash.

Or, if refillable dispenser is being used, use the following:

**Refill Bottle [or Container] [or Jug] Disposal:** Rinse cracked or broken containers and offer for recycling. If recycling is not available, discard in trash.

#### Areas of Use:

Hospital and Healthcare Settings: May be used on hard, nonporous surfaces in: Ambulances, Ambulatory Surgical Centers (ASC), Anesthesia, CAT Labs, CCU, Central Supply, Clinics, Dental Offices, Dialysis Clinics, Doctors' Offices, Donation Centers [blood][plasma][semen][milk][apheresis], Emergency Medical Settings, Emergency Rooms, E.R., Emergency Vehicles, Eye Surgical Centers, Healthcare Settings, Health Care Facilities, Home Health Care, Hospices, Hospitals, ICU, Isolation Areas, Laboratory, Laundry rooms, Long Term Care Centers, Medical Intensive Care Units (MICU), Neonatal Intensive Care Units (NICU), Newborn nursery, Nursing homes, Operating Rooms (OR), Oncology Facilities, Ophthalmic Offices, Orthopedics, Out-Patient Surgical Centers (OPSC), Patient Care Areas, Pediatrics, Pediatric Intensive Care Units (PICU), Physical therapy, Physicians' offices, Radiology, Recovery Rooms, Rehabilitation, Respiratory therapy, Skilled Nursing Facility, Surgery, Surgery Intensive Care Unit (SICU), Surgical Centers, Transport vehicles, Urgent Care Centers, and

X-Ray. and/or

**Critical Care Areas:** CCU, Emergency Rooms, E.R., ICU, Medical Intensive Care Units (MICU), Neonatal Intensive Care Units (NICU), Operating Rooms, Post-Operative Care Unit (PACU), Pediatric Intensive Care Units (PICU), Surgery and Surgical Intensive Care Unit (SICU).

And

Hospital, Healthcare, and Critical Care Use Sites: May be used on hard nonporous surfaces of: ambulance equipment surfaces; bed railings; bladder scan; blood glucose meters; blood pressure cuffs; cabinets; cardiac gym equipment; carts; chairs; cardiac monitors; workstations on wheels (WOW); counters; defibrillators; dental chairs; dental countertops; dental unit instrument trays; dopplers; electronic thermometers; endodontic equipment such as apex locators; exam tables; gurneys; infant incubators [interior and exterior surfaces of]; infant warmers [interior and exterior surfaces of]; isolettes; IV poles; IV pumps; laboratory equipment and surfaces; loupes; operating room tables and lights; operatory light switches; Ophthalmoscopes; Otoscopes; oxygen hoods; physical therapy (PT) equipment surfaces; patient lift equipment; pulse oximeter; radiology equipment; slit lamps; spine back boards; stethoscopes; stretchers; stools; tables; telemetry equipment; telephones; toilet seats; tympanic thermometers; and hard nonporous outside surfaces of: amalgamators and dental curing lights; anesthesia machines and respiratory therapy equipment; apheresis machines, diagnostic equipment, dialysis machines; patient monitoring equipment, patient support and delivery equipment, pulp testers and motors; toilets; ultrasound monitors; and ultrasound transducers and probes.

Grocery Stores *or* Shopping Centers *or* Supermarkets *or* Delicatessens: Disinfects hard, nonporous surfaces such as grocery cart handles and grocery cart child seats. Disinfects shopping cart handles and child seats.

**Nursery or Daycare Centers:** disinfect hard, nonporous surfaces such as bassinets [interior and exterior surfaces of], changing tables, cribs, diaper changing stations, diaper pails, infant/child care equipment surfaces, trash cans, toys and other hard, nonporous surfaces listed on this label.

**Bathroom[s] or Public Restrooms:** disinfect hard, nonporous surfaces such as basins, [bath]tubs, bathroom fixtures, cabinets, countertops, doorknobs, faucet[s], handles, hampers, handrails, shower[s] [stalls], showers, sinks, glazed tiled walls, glazed tiles, toilet [handle] [rim] [seats] [tank] [and other exterior surfaces of], urinals [exterior surfaces of] and vanity tops, and other hard nonporous surfaces listed on this label.

**Health club facilities, Fitness Centers, and Gyms**: disinfect hard, nonporous surfaces such as gym equipment, weight-lifting surfaces and other hard nonporous surfaces listed on this label.

PDI/9480-14/labels February 22, 2018 Page 4 of 10

Schools or Classrooms or Churches or Office Buildings or Public Facilities or Manufacturing Facilities or Libraries or Public Telephones: disinfect hard, nonporous surfaces such as cabinets, chairs, computers, computer monitors, computer mouses, counters, countertops, desks, desktops, doorknobs, fax machines, filing cabinets, filing doors, filing handles, garbage cans, headsets, keyboards, railings, seats, sinks, tables, tabletops, telephones, toys, trash cans, work stations, and other hard nonporous surfaces listed on this label.

Transport vehicles, school buses, public buses, fire trucks, police cars, airplanes, cruise ships, cargo vessels: Hard nonporous surfaces of vehicles including steering wheel, hard plastic or metal flooring, seats, and walls.

**Restaurants:** Hard nonporous, nonfood contact surfaces only including chairs, display cabinets, garbage cans, booster seats, floor, sinks, bathroom surfaces, glazed tiled walls, telephones, cash registers, and doorknobs.

[Symbols including asterisks, bullets or footnotes and similar may be used to designate categories of organisms.]
[ATCC numbers are not required to be listed on production label. Organisms may be listed in a table and in any order.]

#### Antibiotic Resistant Bacteria [(1 Minute Contact Time)]

Acinetobacter baumannii - Multidrug Resistant (MDR) [ATCC 19606] [Effective against organism resistant to Gentamicin, Trimethoprim/Sulfa and Intermediate resistance to Cefepime, Ceftazidime, Ceftriaxone]

Carbapenem Resistant - Klebsiella pneumoniae [(CRKP)] [ATCC BAA-1705]

ESBL Positive Escherichia coli [ATCC BAA-196]

Methicillin Resistant Staphylococcus aureus (MRSA) [ATCC 33592]

NDM-1- Positive Enterobacter cloacae [CDC 1000654]

Vancomycin Resistant Enterococcus faecalis (VRE) [ATCC 51575]

#### Bacteria [(1 Minute Contact Time)]

Pseudomonas aeruginosa [ATCC 15442] Salmonella enterica [ATCC 10708] Staphylococcus aureus [ATCC 6538]

#### Bloodborne Pathogens [(1 Minute Contact Time)]

\*Hepatitis B virus (HBV) - Duck HBV† [Strain 11/04/12] \*HIV-1† (AIDS virus) [Strain HTLV-III<sub>B</sub>]

#### Non-Enveloped Viruses\* [(1 Minute Contact Time)]

\*Adenovirus type 5 [ATCC VR-5] [Strain Adenoid 75]

\*Rhinovirus type 1<sub>A</sub> [ATCC VR-1559] [Strain 2060]

\*Rotavirus [ATCC VR-2018] [Strain WA]

\* Norovirus (Feline Calicivirus) [ATCC VR-782] [Strain F-9]

Enveloped Viruses\* [(1 Minute Contact Time)]

\*Herpes Simplex virus type 2 [ATCC VR-734] [Strain G]

\*Influenza A virus (H3N2) / Strain A/Hong Kong 8/68 [ATCC VR-544]

\*Respiratory Syncytial virus (RSV) [ATCC VR-26], [Strain Long]

#### Pathogenic Fungi [(1 Minute Contact Time)]

Candida albicans [ATCC 10231]

*Trichophyton intergitale* [[(Formerly known as] [(Tested as] *Trichophyton mentagrophytes*)] [ATCC 9533]

## Mycobacterium (TB) [Tuberculocidal] [(1 Minute Contact Time)]

*Mycobacterium bovis* BCG (Tuberculosis) (TB) [Organon Teknika]

#### C.difficile Spores [(5 Minute Contact Time)]

Clostridium difficile spores [ATCC 43598]

[Effective against all listed organisms in the presence of organic soil (5% blood serum)] [Optional organism listings and claims:]

[\*][Product name] is virucidal against Adenovirus type 5, Hepatitis B virus (HBV),), Herpes Simplex Virus type 2 (causative agent of genital herpes), HIV-1, Influenza A virus (H3N2)/Hong Kong strain (representative of the common flu virus), Respiratory Syncytial Virus [RSV], Rhinovirus type 1a, Rotavirus (Strain WA), in the presence of organic soil (5% blood serum).

[*Product name*] is a germicidal liquid containing a Hydrogen peroxide based solution. Recommended for use in hospitals and other critical care areas where the control of the hazards of cross-contamination between treated surfaces is required. Use on hard nonporous surfaces and equipment listed on this label made of stainless steel, plastic, Formica® and glass. [Formica® is a registered trademark of The Diller Corporation.]

#### The Following Emerging Viral Pathogen Claims Are Optional:

#### **Emerging Viral Pathogen Claims**

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- Enveloped Viruses
- Large, Non-Enveloped Viruses
- Small, Non-Enveloped Viruses

For an emerging viral pathogen that is a/an	follow the directions for use for the following organisms on the label:
Enveloped virus	One of the following: Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5) Rotavirus, Strain WA (ATCC VR-2018) Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)
Large, non-enveloped virus	One of the following: Rhinovirus Type 1A, Strain 2060 (ATCC VR- 1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)
Small, non-enveloped virus	Two of the following: Rhinovirus Type 1A, Strain 2060 (ATCC VR- 1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [porous and/or nonporous surfaces]. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/nonporous surfaces]. Refer to the [CDC or OIE] website at [pathogen specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product Name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/nonporous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

PDI/9480-14/labels February 22, 2018 Page 6 of 10

<u>Optional Claims and Descriptors</u> [Note: Deodorizing directions must be used when deodorizing claims (claims involving odor control) are used]

© [insert year] [insert company name]

Always ready to use

An effective method to deodorize and disinfect against odor-causing organisms on hard, nonporous surfaces [listed on this label]

An effective way to disinfect hard, nonporous environmental surfaces listed on this label.

Antibacterial

Antimicrobial

[Antibacterial] [Antimicrobial] health club equipment spray

A Sani-Surface® Brand

[Bactericidal], [Tuberculocidal], [Fungicidal] [Virucidal\*] in 1 [one] minute

Bactericidal

Bleach-free [formula] [this is included as useful info for users needing a bleach-free product]

Broad spectrum [microorganism coverage]

**Broad Spectrum Disinfectant** 

Broad spectrum efficacy

Brought to you by [Sani-Cloth® Brand] [PDI] [Sani Professional]

Can help reduce the risk of cross contamination on treated hard, nonporous surfaces

Cleans [as it disinfects] [and disinfects]

Cleans [,] [Deodorizes,] and kills common household germs<sup>+</sup> [use at least two bacteria and two viruses from the organism list]

Compatible for use on hard, nonporous surfaces commonly found in healthcare settings [listed on this label]

Completely inactivates [viruses\*] [insert virus(es)\*]

Contains [number] bottles [plus] [and] [number] [refills]

Contains no VOC-emitting ingredients

Convenient

Demonstrates 6 [six] log reduction against [Clostridium difficile] [C. difficile] [C.diff] spores in [5] [five] minutes

Demonstrates 99.9% reduction of [bacteria] [insert bacteria]

Deodorize hard, nonporous surfaces [Use to]

Deodorizes [,] [cleans,] and kills common household germs\* [use at least two bacteria and two viruses from the organism list]

Designed for killing [Clostridium difficile] [C. difficile] [C.diff] spores on hard, nonporous surfaces in hospitals

Destroys [Deactivates] [[Helps] Eliminate] [Clostridium difficile spores] [C.difficile spores] [C.diff spores] [-

hard, nonporous surfaces in hospital

Disinfect external hard, nonporous surfaces of ultrasound transducers

Disinfects precleaned hard, nonporous surfaces

Disinfectant spray

Disinfects [,] [cleans] [and deodorizes] [hard] nonporous surface(s)] [that people touch] in [just] 1 minute.

Disinfects [grocery cart handles] [shopping cart handles] [grocery cart child seats] [shopping cart child seats]

[Disinfects] hard, nonporous surfaces

Disinfects [health club equipment] [treadmill handles] [elliptical handles] [exercise bike handles] [weight benches]

Disinfects on the go

Do not use on natural marble, windows, unpainted wood, brass, clear plastic, or colored grout.

Does not contain bleach [this is included as useful info for users needing a bleach-free product]

[Easy] [Convenient] [Portable] way to disinfect hard, nonporous surfaces

Easy [and convenient] way to [touch-up] [bathroom] [office] [and other sites listed on this label] everyday

Easy [to use] [to refill]

Easy to use trigger spray

[Economical] Refills [now] available

Effective against bacteria and viruses\* [use at least two bacteria and two viruses from the organism list]

Effective against [Clostridium difficile] [C.difficile] [C.diff] spores [fin [5] [five] minutes]

Effective against [:] [the following micro-organisms] [list organisms]

on hard, nonporous surfaces [list organisms]

Effective in the presence of 5% blood serum contamination

Eliminates odors

Eliminates daily mixing and measuring

Eliminates [lingering] [food] odors on surfaces

Environmental services use

Exclusive to PDI, Inc.

Expiration date [or EXP] [insert date]

[For] daily use

For [hospital] [healthcare] use

[For] nonfood contact surfaces [only]

From the makers of Sani-Cloth® Brand

#### Fungicidal

[Gets rid of] [Eliminates] odors

Germicidal<sup>+</sup> [Spray] [use at least two bacteria and two viruses from the organism list]

Hard, nonporous surface disinfectant

[Helps] [kill(s)] [eliminate(s)] odor-causing bacteria

Helps prevent cross contamination on hard nonporous treated surfaces

Hospital [disinfectant] [disinfection] [disinfectant-cleaner] [use only when hospital use sites on label]

[Ideal] for use on high-touch, hard, nonporous surfaces

Kills bacteria and viruses\* [in the bathroom] [on the exterior toilet surfaces] [use at least two bacteria and two viruses from the organism list:]

Kills bacteria [in 1 minute]

Kills [Clostridium difficile] [C. difficile] [C.diff] spores [in [5] [five] minutes]

[Kills] [Disinfects] Norovirus [Feline Calicivirus] [in] 1 [one] minute

[Kills] [Effective against] 99.9999% of [Clostridium difficile] [C. difficile] [C.diff] spores in [5] [five] minutes

[Kills] [Effective against] MRSA [(Methicillin Resistant Staphylococcus aureus)] in 1 (one) minute

[Kills] [Effective against] CRKP [(Carbapenem Resistant Klebsiella pneumoniae)] in 1(one) minute

Kills odor causing bacteria

[Kills] [Effective against] TB [in [1] [one] minute]

[Kills] [Effective against] the spore form of Clostridium difficile [or C. difficile]

[Kills] [Effective against] viruses\* [in [only] [1] [one] minute]

Leaves [bathroom] [office] [and other sites listed on this label] disinfected [and smelling fresh]

[Made in USA] [Of Domestic and [Foreign] [Imported] Materials] [Made in [insert country]]

Meets OSHA Bloodborne Pathogen Standard [or AHE Practice Guidance for environmental cleaning] [CDC Guidelines for disinfection and sterilization in healthcare settings]

Multi-pack

Multi-purpose disinfectant

[Multi [-refill] pack]

New (may be used for 6 months on marketed label)

No diluting or mixing required

Non-Bleach [this is included as useful info for users needing a bleach-free product]

Non-Bleach Sporicidal<sup>^</sup> (^ [Clostridium difficile] or [C. difficile] spores) [hospital] [disinfectant] [this is included as useful info for users needing a bleach-free product]

Non-corrosive

Not available in private label

Not for sale in [insert name of state(s)]

Not for sale [or use] after [insert date]

Odor [eliminator] [neutralizer]

One-Step Cleaner/Disinfectant [Grease and soap scum claims are not to be used on labeling with one-step cleaning/disinfection claims. One step cleaner/disinfectant claim should not be used for C.difficile.]

Overall [5] [five] minute contact time

[Package] [insert type of package] made from [x%] recycled materials

Perfect for disinfecting [exterior toilet surfaces] [around the exterior toilet surface]

Powers through tough messes

Proprietary Formulation [product]

Ready to Use [disinfectant] [spray]

Recyclable [package]

Reduce [risk of] cross contamination on hard, nonporous surfaces.

Reduces exposure to microorganism(s) from treated surface

[Refill] package contains [various numbers] [refill(s)]

Refill [size] [pack] [value pack]

Removes [odors] [dirt]

Shelf-Stable formula

Sporicidal<sup>^</sup> (<sup>^</sup> [Clostridium difficile] or [C. difficile] spores)

The 5-minute [germicidal\* spray] [disinfectant spray]

Trial [pack]

Tuberculocidal

Twin pack

Use by [insert date]

Use on hard, nonporous surfaces only: [stainless steel] [Formica®] [glass] [glass tables] [glazed tile] [Test solution on a small inconspicuous area first.] [Formica® is a registered trademark of The Diller Corporation.]

[Use to] disinfect(s) hard, nonporous environmental surfaces listed on this label

Use to preclean or decontaminate critical or semi-critical medical devices prior to sterilization / high-level disinfection

Value

Versatile

Virucidal\*

Where control of the hazards of cross contamination between treated surfaces is of prime importance With a bleach-free formula [this is included as useful info for users needing a bleach-free product]

#### Master Label Reader Notes

Statements in brackets [ ] are optional or instructional.

[A footnote can be used to list organisms. Bacteria and virus can be separated into footnotes 1 and 2 if desired.]
[When organisms are listed next to a claim, the organisms may be listed in a footnote instead of directly next to the claim]
[† All pesticidal "germ" claims must be linked to bacteria (minimum: Salmonella and Staph) and at least one virus. For example: Front panel: "Kills germs\*" Back panel: "Kills Salmonella enterica, Staphylococcus aureus, Herpes Simplex Virus Type 2, and Influenza A/Hong Kong"].

PDI/9480-14/labels February 22, 2018 Page 9 of 10

[Graphics depicting use sites listed on this label can appear on product label and labeling.] The following graphics and statements are optional. They may be placed anywhere on label/container.]

### FOR USE ON HARD, NONPOROUS SURFACES ONLY

### Do not freeze

### Do not allow to freeze









[The following are company logos for use on PDI product labels. The purpose of the logo is for easy recognition of PDI products in the marketplace.]





PDI/9480-14/labels February 22, 2018 Page 10 of 10